

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-18	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date: July 6, 2018
--	--------------	---

TABLE OF CONTENTS

SECTION		Page
I.	Purpose	2
II.	Procedures	2
	A. Vaccine Administration Documentation	2
	1. Electronic Immunization Clinic Record Form (DH 687)	2
	2. Florida SHOTS Notification and Opt-Out Form (DH 1478)	3
	3. Religious Exemption from Immunization Form (DH 681)	4
	4. Immunization History Update	4
	5. Eligibility for Vaccines for Children (VFC) Program	4
	6. Distribution of Risk/Benefit Information	5
	7. Vaccine Administration	7
	8. Documentation of Doses Given	7
	9. Family Planning/STD Confidential Minors and Immunizations	8
	10. Post-Vaccination Parent/guardian Counseling	9
	B. Vaccine Adverse Event Reporting System (VAERS)	9
III.	Scope	11
	A. Personnel	12
	B. Competencies	12
	C. Areas of Responsibility	12
IV.	Authority	12
V.	Supportive Data	12
VI.	Distribution List	13
VII.	History Notes	13

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-18	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date:
---	--------------	---

I. Purpose

To administer vaccines according to the current standard of care, to document all vaccines administered in the CHD, to ensure distribution of risk/benefit information to clients, and to report adverse events.

II. Procedures

Department of Health (DOH) county health department (CHD) staff will administer vaccines according to the current standard of care and document administration of all vaccines administered to CHD clients. All clients or their parent/guardian will be informed of the risks and benefits of each vaccine to be administered. The current Vaccine Information Statement (VIS), prepared by the Centers for Disease Control and Prevention (CDC), will be provided to the client or their parent/guardian. Adverse events associated with the administration of certain vaccines will be reported to the Vaccine Adverse Event Reporting System (VAERS).

A. Vaccine Administration Documentation

Each CHD is required to obtain consent for treatment and care, including immunization services, for all clients receiving immunizations. Documenting consent in the Florida State Health Online Tracking System (SHOTS) is recommended and suffices for electronic signature. The current Department of Children and Families Operating Procedure details statutory authority and outlines under which circumstances a foster parent or shelter care worker may sign to authorize needed immunizations. Contact the local Department of Children and Families district office for specific guidance at <http://www.myflfamilies.com/contact-us>.

An education plan that includes competency-based training on vaccine administration should be developed and implemented for all CHD staff who administer vaccines. Individuals shall maintain records of all training documentation in the event of an audit.

When a client presents for immunizations, all client identification and historical immunization data should be reviewed and updated, as needed.

1. Electronic Immunization Clinic Record Form (DH 687)

- a. The Immunization Clinic Record is the permanent medical record for a client's immunizations. The Health Management System (HMS) documents all client services, and Florida SHOTS is used to document historical and administered vaccines.
- b. It is not necessary to maintain a hard copy of current immunizations if the electronic DH 687 form within Florida SHOTS is used.
- c. Enter data in Florida SHOTS according to the guidelines in this policy. All client and immunization information should be entered into Florida SHOTS as soon as possible, preferably during the administration process or at least the same day.

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-18	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date:
--	--------------	--

- d. Florida SHOTS-generated DH 687 form can be printed, if a hard copy is necessary. All doses of all vaccines administered will be documented on this form.
2. Florida SHOTS Notification and Opt-Out Form (DH 1478)
 - a. Effective January 1, 2003, all children born in Florida are added to Florida SHOTS as required by section 381.003, Florida Statutes, and Florida Administrative Code Rule 64D-3.046. The Bureau of Vital Statistics provides a birth file for all children born on or after January 1, 2003, for loading into Florida SHOTS. Opt-out forms for these children are provided by the Bureau of Vital Statistics through the birth notice that is mailed to their parent/guardian. The opt-out provision is automatically recorded in Florida SHOTS for these births. There is no need to provide additional opt-out information, unless specifically requested by a parent/guardian. If a parent/guardian does request an opt-out form, the CHD should provide the form and have the parent/guardian follow directions on the form for submission. This form is also available online at <http://flshotsusers.com/opt-out>.
 - b. All staff who administer vaccines must be added as personnel in Florida SHOTS.
 - c. Technical assistance for Florida SHOTS is available from the *DOH Immunization Section User's Guide to Florida SHOTS: Immunization Registry* and the staff at Florida SHOTS enrollment desk (contact 1-877-888-7468 or email DL HSD IMM FLSHOTS HELPDESK). Web-based training for Florida SHOTS is available and recommended for all users.
 - d. When a child's immunization record is added to Florida SHOTS, parent/guardian should receive notification of the ability to opt out of sharing immunization records by filling out and submitting a *Florida SHOTS Notification and Opt-Out* form (DH 1478). This notification is required by section 381.003, Florida Statutes, and Rule 64D-3.046, Florida Administrative Code. Notification can be accomplished by posting a highly visible DH 1478 form at the intake desk where parent/guardian bring children for vaccinations.
 - e. The aforementioned posting of the notification is sufficient for parent/guardian whose children born prior to January 1, 2003, are added to the registry or who present for the first time from another state. The notification date and the name of the individual recording the date should be added to Florida SHOTS when the client is added to the system for the first time. This information will automatically appear on the electronic DH 687 form in view or print mode. (Opt-out information only has to be provided and documented once in Florida SHOTS).

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-18	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date:
--	--------------	--

3. Religious Exemption from Immunization Form (DH 681)

- a. Effective August 14, 2015, when a parent requests *Religious Exemption from Immunization* form (DH 681), CHD staff will provide the department form *Did You Choose Not to Vaccinate Your Child?* (DH8001-DCHP-07/2015), located at http://www.floridahealth.gov/programs-and-services/immunization/publications/_documents/vaccine-responsibilities-ltr-eng.pdf.
- b. This is intended for distribution to DOH clients who exercise their right to opt out of vaccinating their children through a religious exemption. No attestation or signed acknowledgement should be required of clients upon their receipt of the form as it is for educational purposes, not counseling.
- c. If a parent/guardian requests such an exemption, then the CHD staff must use the current DH 681 form available electronically in Florida SHOTS, which the parent/guardian affirms a religious conflict exists. This form must be issued upon request. No other information should be solicited from the parent/guardian.
- d. Document issuance of religious exemption in Florida SHOTS according to guidance in the *DOH Immunization Section User's Guide to Florida SHOTS: Immunization Registry*. Provide a completed *Religious Exemption from Immunization* form (DH 681) and duplicate for client and/or parent/guardian records. Refer to the current *Immunization Guidelines for Florida Schools, Childcare Facilities and Family Daycare Homes* at www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/_documents/school-guide.pdf for additional information.

4. Immunization History Update

- a. Add all historical immunizations given by other clinics or private medical providers into Florida SHOTS, unless already available in the system.
- b. If the client receives services from another provider, instruct the parent/guardian to take the updated immunization record to that practice.
- c. Review Florida SHOTS Immunization Status page to assist in determining vaccines due and recommended due dates. Assess the client's immunization history to determine which vaccine(s) is needed at each encounter. Review all sources of immunization documentation.

5. Eligibility for Vaccines for Children (VFC) Program

- a. Screen clients (birth through 18 years of age) at each clinic visit to determine their eligibility under the VFC Program. Refer to *the Florida Vaccines for*

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-18	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date:
--	--------------	--

Children Program Provider Handbook at www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/vfc-provider-handbook-2016.pdf for details.

- b. Indicate the eligibility status by selecting the appropriate code in Florida SHOTS.

(1) Eligibility categories:

- (a) VFC-Eligible–American Indian or Alaskan Native
- (b) VFC-Eligible–Medicaid/MCO
- (c) VFC-Eligible–Underinsured
- (d) VFC-Eligible–Uninsured

6. Distribution of Risk/Benefit Information

- a. Provision of the Vaccine Information Sheet (VIS)

- (1) By federal law, the National Childhood Vaccine Injury Act requires all vaccine providers to give each patient or their parent/guardian the appropriate CDC VIS form on each occasion a vaccination is given. Florida SHOTS will link to the current version for each vaccine. These forms are available at www.cdc.gov/vaccines/hcp/vis/index.html. Document the VIS given, publication date, to whom the VIS was provided, and the CHD staff providing the VIS in Florida SHOTS. **Note:** Both the consent and VIS receipt should be documented in Florida SHOTS.
- (2) Allow the client **or** parent/guardian sufficient time to read the VIS. Providers should supplement VIS forms orally, with videotapes, additional printed material, or any other way that will help the client and parent/guardian understand the disease and vaccine, as needed.
- (3) The CHD clinical staff will answer all questions in a client-friendly, culturally sensitive manner.
- (4) Maintain a translation referral list and information to Language Line Services. Translated versions of the VIS for childhood vaccines are available on-line at www.immunize.org/vis/?f=9.
- (5) In the absence of access to Florida SHOTS, use the hard copy of the DH 687 form. Record the CDC publication date of each VIS provided in the "VIS Date" section on the line corresponding with the vaccine given. Document the required information on the DH 687 form after the client and/or parent/guardian have been provided and s/he has read the applicable VIS.

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-18	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date:
--	--------------	--

7. Vaccine Administration

- a. The CHD clinical staff will administer the appropriate vaccines according to the current standard of care, the current *ACIP Recommended Immunization Schedules for Persons Aged 0 through 18 years, United States*, and the latest *Report of the Committee on Infectious Diseases of the American Academy of Pediatrics (Red Book)*. The CHD staff will also document administration of all vaccines administered to CHD clients.
- b. Upon review all sources of immunization documentation and assessment of the client's immunization status, CHD staff will determine which vaccine(s) is (are) needed at each encounter.
- c. CHD staff will provide the needed vaccine(s) according to the CHD's internal standing orders for administering the age-appropriate vaccine(s) due at the time of the encounter. Under these standing orders, eligible CHD clinical staff may vaccinate children and teens who meet any of the criteria.
- d. Screen all patients for contraindications and precautions to the age-appropriate vaccine(s) due at the time of the encounter.

8. Documentation of Doses Given

- a. Only Florida SHOTS registry should be used for documentation of immunizations.
- b. Choose the appropriate vaccine administration route/site from Florida SHOTS. A listing of approved abbreviations is located in the Department of Health Policy (DOHP) 380-3-14, Clinical Abbreviations/Acronyms/Symbols Policy, available at dohwebdev.doh.ad.state.fl.us/Divisions/Planning_Evaluation/HPE_DOHPolicy/DOHP380-3.pdf.
- c. Varicella Disease: If the client has a valid history of varicella disease, it should be entered as a contraindication by recording the date and source of history (that is physician documentation) in the varicella section in Florida SHOTS.
- d. If using combination vaccines, verify that administration of each antigen is documented. In the absence of access to Florida SHOTS, verify that all information for each antigen is recorded on a hard copy DH 687 form. A blank DH 687 form can be printed from Florida SHOTS.
- e. Inquire about and record all conditions that may indicate allergies, contraindications, and permanent medical exemptions. Reference the list of valid precautions and contraindications from the CDC website at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html>.

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-18	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date:
--	--------------	--

- f. A Florida SHOTS-generated *Florida Certification of Immunization* form (DH 680) can be provided to the parent/guardian, if needed. Only valid doses of vaccines required for school or child care appear on this form.
 - g. Parent/guardian may be issued a DH 680 personal identification number by the CHD or other health care provider for later retrieval of the DH 680 form directly by the parent/guardian.
 - h. A Florida SHOTS-generated report, *Immunization History* form (DH 686) can be printed and provided to the parent/guardian, as a personal immunization record. All valid doses of vaccines received and recommended next due dates are listed on this form.
 - i. If the client is a Women, Infants and Children Program (WIC) client, add the WIC identification number, if known.
9. Family Planning/STD Confidential Minors and Immunizations
- a. The provider must document in the notes that the confidential minor seeking Family Planning/STD services meets the requirements of the statute, as reflected in TAG 332-4 FAMPLAN4 paragraph C, and has been informed of risks/benefits of the vaccine and given informed consent.
 - b. Confidential Family Planning/STD minor clients may receive the human papillomavirus (HPV) vaccine and the hepatitis B vaccine without parental consent.
 - c. An uninsured minor (under 19 years of age) may receive these vaccines through a Title X Family Planning/STD Clinic. If an insured minor desires vaccination, but does not have access to the insurance because of confidential circumstances (seeking family planning or STD services), the minor is considered uninsured, which meets eligibility for VFC-funded (PC 01) vaccine. Minors who are insured by Medicaid are also eligible for VFC-funded (PC 01) vaccine.
 - d. If a confidential minor begins vaccination series as a Family Planning/STD client, then the minor must complete vaccination series as a Family Planning/STD client. A confidential Family Planning/STD minor client must not be referred to CHD Immunization Clinics to receive follow-up series vaccinations.
 - e. Documentation of immunizations for confidential Family Planning/STD minor clients must be performed within the clients' electronic health record in Medication Profile/Emdeon and not entered into FLSHOTS.
 - f. Within Medication in HMS, choose Standard/Reported. Do not choose minors insurance unless it is Medicaid. On the RxPad page, choose the

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-18	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date:
--	--------------	--

“Reported RX” button on the right-hand side of the screen. Complete Effective Date; enter vaccination type under DRUG. This will record the name of the vaccine and the dose given. Record the following under Notes to Pharmacist:

(1) Vaccination Information Statement with publication date given to client

(2) Injection site

(3) Injection route

(4) Name of vaccine manufacturer

(5) Vaccine lot number

(6) Expiration date

(7) NDC number

(8) Name and title of vaccinator

(9) Dose sequence (first, second, or third)

(10) Next Dose in number weeks or months (for the second and third doses)
EXAMPLE: HPV VIS (11/15/15) given to client; RDT; IM; Merck & Co; Lot# L018351; Exp 8/11/17; NDC 00006-4119-03; Administered by J. Smith, RN; 1st dose. Next Dose in X weeks.

NOTE: There is limited space in comments and this information must be entered as indicated with no returns

REMOVE PHARMACY by clicking the black X
SAVE.

g. CHDs should follow the guidance provided in the *Florida VFC Provider Handbook* for inventory management.

h. Reimbursement of HPV and hepatitis B vaccination services for confidential Family Planning/STD minor clients is limited to billing Medicaid for the administration fee only.

i. Recommended confidential minor immunization guidelines:

(1) Female confidential Family Planning/STD minor clients aged 11–17 years:

(a) Should be offered either VFC-funded (PC 01) HPV vaccine for prevention of HPV and cervical cancer if not previously vaccinated.

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-18	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date:
--	--------------	--

(b) Should be offered VFC-funded (PC 01) hepatitis B vaccination if not previously vaccinated

(2) Male confidential Family Planning/STD minor clients aged 11–17 years:

(a) Should be offered VFC-funded (PC 01) HPV vaccine, if not previously vaccinated.

(b) Should be offered VFC-funded (PC 01) hepatitis B vaccination if not previously vaccinated.

10. Post-Vaccination Parent/Guardian Counseling

- a. Provide client or parent/guardian with information (oral or written) on common adverse events, which may follow immunization.
- b. In case of an adverse event following vaccine administration, provide client or parent/guardian with telephone numbers and explain where and how to obtain medical care during daytime and nighttime hours. Please instruct client or parent/guardian to contact the CHD if any adverse event occurs.
- c. Follow-up activities, such as telephone calls, reminder/recall notices, and home visits, should be documented under contact attempts in Florida SHOTS and/or in the medical record.

B. Vaccine Adverse Event Reporting System (VAERS)

1. The VAERS is a passive surveillance system through which individuals report events associated with the administration of certain vaccines.
2. According to the National Childhood Vaccine Injury Act, you must report specific adverse events following the administration of specific vaccines in accordance with recommendations provided in the *Morbidity and Mortality Weekly Report (MMWR)* Volume 60, No. RR-2, January 28, 2011.
3. The VAERS accepts all reports of adverse events after the administration of any vaccine.
4. Any serious adverse events, such as those that require a health care visit, should be reported through the VAERS.
5. Health care providers, including CHD staff, are required by law to report certain adverse events.
6. Lay people, such as parent/guardian, may also report adverse events to the VAERS. Encourage these individuals to seek the assistance of a health professional in completing the form.

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-18	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date:
--	--------------	--

a. VAERS Forms

- (1) The VAERS reports are submitted electronically at vaers.hhs.gov/index.
- (2) For non-electronic submission, copies of the VAERS reporting form and instructions can be found and downloaded from vaers.hhs.gov/, by calling toll-free 1-800-822-7967, or by submitting requests to the VAERS at info@vaers.org.

b. Reporting Process

(1) CHD Staff Responsibilities:

- (a) Initiate and complete electronic VAERS report submission according to the instructions.
- (b) Print and review the form to ensure that all items are complete. Be sure the dates make chronological sense. For example, the date of birth must precede the date of vaccination. This information is critical to the analysis of the VAERS data.
- (c) Notify the CHD VAERS coordinator and the Immunization Section VAERS coordinator.
- (d) Submit a completed report to VAERS, the Immunization Section VAERS coordinator, and retain a copy for case management.

c. Each CHD will appoint a VAERS Coordinator responsible for:

- (1) Receiving VAERS notification from all CHD clinics in the county.
- (2) Reviewing the report for completeness, accuracy, and consistency.
- (3) Verifying electronic VAERS submission and notification to Immunization Section VAERS Coordinator.
- (4) Identify a designated backup staff. Cross training these duties ensures timely and accurate reporting. Performance standards should reflect these responsibilities for the designated individuals.
- (5) Enter adverse event(s) into Florida SHOTS on behalf of the client.

d. Follow Up of Serious Adverse Events

- (1) Certain serious adverse events require a 60-day and/or one-year follow up. The parameters for follow-up reporting are determined by the VAERS on a case-by-case basis.

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-18	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date:
---	--------------	---

- (2) The Immunization Section VAERS Coordinator will notify the CHD VAERS Coordinator when follow up is due, so that the CHD coordinator can obtain information on the status of the client and report findings back to the Immunization Section VAERS Coordinator.

III. Scope

- A. Personnel: All CHD Medical Doctors (MD), Doctors of Osteopathy (DO), Advanced Registered Nurse Practitioners (ARNP), Physician’s Assistants (PA), Registered Nurses (RN), and Licensed Practical Nurses (LPN) within constraints of their practice acts, protocols, and responsibilities for immunization services.
- B. Competencies: The CHD management team is responsible for determining the level of knowledge and competency of staff members providing immunization services.
- C. Areas of Responsibility:
 - 1. Distribution of Risk/Benefit Information: Each CHD provider is responsible for ensuring documentation of receipt of the appropriate VIS prior to each vaccination administration under federal law.
 - 2. Vaccine Administration: The CHD immunizations staff is responsible for administering vaccines according to the current standard of care and following the ACIP recommendations.
 - 3. Vaccine Administration Documentation: Each CHD is responsible for maintaining proper documentation of vaccine administration.
 - 4. Vaccine Adverse Event Reporting System: CHD staff is responsible for reporting certain adverse events under federal law.

IV. Authority: Sections 381.0011, 381.003, and 1003.22, Florida Statutes, and Florida Administrative Code Rule 640-3.046.

V. Supportive Data

- A. *Epidemiology and Prevention of Vaccine-Preventable Diseases* (The 2015 Pink Book): Vaccine Administration Chapter of Pink Book, 13th edition, 2015; www.cdc.gov/vaccines/pubs/pinkbook/index.html, accessed 05/18.
- B. *User’s Guide to Florida SHOTS: Immunization Registry*, www.flshotsusers.com/, accessed 05/18.
- C. Department of Health, Health Management System, *Clinical Portal Overview*, dohiws/Divisions/Planning_Evaluation/HMS/Training/UserDocumentation/ClinicalEncounter/ClinicianPortal_Overview.pdf, accessed 05/18.

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-18	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date:
--	--------------	--

- D. Vaccine Adverse Event Reporting System, vaers.hhs.gov/, accessed 05/18.
- E. *Immunization Guidelines for Florida Schools, Childcare Facilities and Family Daycare Homes* at www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/_documents/school-guide.pdf, accessed 05/18.
- F. CDC Vaccines for Children Program Operations Guide, www.cdc.gov/vaccines/programs/vfc/index.html, and www.cdc.gov/vaccines/programs/vfc/awardees/index.html, accessed 05/18.
- G. *Florida Vaccines for Children Program Provider Handbook*, www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/vfc-provider-handbook-2016.pdf, accessed 05/18.
- H. Centers for Disease Control and Prevention, www.cdc.gov, accessed 05/18.
- I. Centers for Disease Control and Prevention, *Mortality and Morbidity Weekly Report*, www.cdc.gov/mmwr, accessed 05/18.
- J. Florida Department of Children and Families Operating Procedures, www.dcf.state.fl.us/admin/publications/policies.asp, accessed 05/18.

VI. Distribution List

Deputy Secretary for Health
 Division of Disease Control and Health Protection
 County Health Department Directors/Administrators
 County Health Department Medical Directors
 County Health Department Nursing Directors
 Children's Medical Services Medical Directors
 Children's Medical Services Nursing Directors
 Children's Medical Services Program Managers

VII. History Notes

This IOP replaces and supersedes IOP 350-5-16 dated June 30, 2016 and its predecessor DOHP 350-5-14 dated February 23, 2014.

VIII. Signature and Effective Date

Signature on File

Carina Blackmore, DVM, PhD, Dipl ACVPM
Director, Division of Disease Control and Health Protection

July 06, 2018

Date

MESH "CHD Guidebook" DCHP BOE Immunizations VFC "Vaccines For Children" VAERS "VAERS follow-up" reminder recall "VIS documentation" "combination vaccine" "immunization card" "immunization route" "immunization clinic" "vaccine documentation" "DH 687" "DH 681" "religious exemption" FLSHOTS "Immun IOP 350-5"